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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,520	03/16/2004	Eric Leopold	MICRU:68082	3981

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EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/802,520	Applicant(s) LEOPOLD ET AL.	
	Examiner Natalie Pous	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/13/2002, 6/12/02</u> | 6) <input checked="" type="checkbox"/> Other: <u>3/6/2003</u> |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "most" in claims 16 and 24 is a relative term which renders the claim indefinite. The term "most" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what the term "most" refers to in the claim, because "most" refers to the majority which can be from 50 to 100 percent. In addition, no sheath length is specified, therefore making the relative term "most" indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 16, 19-21 and 26-28 rejected under 35 U.S.C. 102(a) as being anticipated by Diaz et al (US 20040087964).

Regarding claim 16, Diaz discloses

A sheath (50) in combination with a vasoocclusive device (50), the vasoocclusive device including an assembly of a flexible pusher member (44) and an embolic coil (44) that is adapted to be inserted into a portion of a vasculature for occluding a portion of the vasculature for use in interventional therapy and vascular surgery, the sheath comprising:

a hollow, elongated tubular member having opposing upper and lower walls, opposing side walls (12), and a longitudinal interior channel (14), and a longitudinal slot (36) formed in the upper wall of the elongated tubular member and extending most of the length of elongated tubular member, leaving up to about 10cm with no slot (Page 4, paragraph 42), the slot having opposing sides with inner side surfaces extending through the upper wall of the elongated tubular member leading to the interior channel (12) permitting introduction of the vasoocclusive device into the interior channel.

Regarding Claims 19 and 26, Diaz teaches the sheath of Claim 16, wherein the outside diameter is approximately .003 inches, and wherein the inside diameter is slightly greater than that of a deployment catheter (Page4, paragraph 42), corresponding to the lower wall of the hollow, elongated tubular member (12) being about 0.002 to 0.004 inches thick to allow the opposing sides of the slot of the hollow,

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elongated tubular member to flex outwardly to allow the slot to open to accept the vasoocclusive device (Page 2, paragraph 14).

Regarding Claims 20, 21, 27 and 28 Diaz teaches the sheath of Claim 16, wherein the hollow, elongated tubular member is formed from a polymer material with a durometer in the range of about 50D and 70D (page 4, paragraph 42). High-density polyethylene is a type of thermoplastic polymer and has a durometer of between 61D and 63D, falling in the disclosed range.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17, 18, 22, 23, and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz in view of Ahmed (5293713)

Diaz teaches all elements of claim 16, but lacks the use of an angle-configured guide as disclosed in claims 16 and 25. Ahmed teaches the use of angled winged flanges. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide Diaz with the winged flanges as taught by Ahmed in order to enhance guiding the element as the element is pushed through the opening (Col. 2 lines 68-70).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angles of the opening between 110 to 150 degrees, since it has been held that where the general condition of the claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No.

6716223. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 18-23 and claims 25-30 of the application are duplicates of claims 2-6 of the patent, and claims 16, 17 and 24 of the application are not patentably distinct from claim 1 of the patent. Claims 16 and 24 of the application state "most of the length of elongated tubular member, leaving up to about 10cm with no slot," while claim 1 states "a first portion of the length, leaving a second portion with no slot." Claims 16 and 24 are inherently encompassed by claim 1 of the patent, rendering the application not patentably distinct from the patent.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP
9/20/05


primary Art Unit 3731
9/21/05